



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,312	12/30/2003	Jessica R. DesNoyer	50623.313	1694

7590 10/04/2006
Cameron Kerrigan
Squire, Sanders & Dempsey L.L.P.
One Maritime Plaza, Suite 300
San Francisco, CA 94111

EXAMINER

LAMB, BRENDA A

ART UNIT PAPER NUMBER

1734

DATE MAILED: 10/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/750,312

Applicant(s)

DESNOYER ET AL.

Examiner

Brenda A. Lamb

Art Unit

1734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-9,11,13,14 and 18-25 is/are pending in the application.
- 4a) Of the above claim(s) 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-9,11,13,14 and 19-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/12/2006 has been entered.

Applicant has elected in the response to the restriction requirement, paper received 5/25/2005, the species as exemplified in Figures 7A-7C and 5A-5C. Applicant has amended claim 18 to recite mandrel to support the stent is comprised of a member to penetrate at least partially into a longitudinal bore of the stent during the application of a coating substance, the member including 3 outward projecting walls, each wall including 3 pairs of opposing parallel sides. Newly amended claim 18 is now directed to non-elected specie since Figures 7A-7C and 5A-5C do not show a member including 3 outward projecting walls, each wall including 3 pairs of opposing parallel sides and therefore claim 18 is withdrawn as being directed to a non-elected specie.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

Art Unit: 1734

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1,4-5,9,11,13-14, 19 and 23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Hattler et al 4,846,791 with Tseng et al 6,364,903 cited to show inherency.

Hattler et al teaches in drawings which include Figures 12-13 stent and a mandrel to support the catheter or stent comprising: a member to penetrate at least partially into a longitudinal bore of a stent, the member including outwardly projecting integral walls disposed around the circumference of the mandrel, wherein each of the walls converge with its neighboring wall at an angle. Hattler et al teaches at column 5 lines 10-15 that the catheter tube or stent supported on the mandrel is radially expandable. Although Hattler et al explicitly fails to teach the stents includes struts as set forth in newly amended claim 23, it would have been inherent Hattler et al stent/catheter tube includes struts since stents have struts as evidenced by Tseng et al. Hattler et al is capable of supporting a catheter or stent during application of coating

Art Unit: 1734

thereon since it teaches every positively claimed element of the apparatus. Note it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ 2d 1647 (1987). With respect to claim 19, Hattler et al teaches as depicted in the drawings which includes Figure 16 the design of a catheter or stent and a mandrel to support the catheter or stent comprising: a member to penetrate at least partially into a longitudinal bore of a stent during the application of a coating substance, the member including 6 sides and each side wall surface is non-parallel with its neighboring side wall surface. Hattler et al teaches at column 5 lines 10-15 that the catheter tube or stent supported on the mandrel is radially expandable. Although Hattler et al explicitly fails to teach the stents includes struts as set forth in newly amended claim 19, it would have been inherent Hattler et al stent/catheter tube includes struts since stents have struts as evidenced by Tseng et al. Hattler et al is capable of support the catheter or stent during application of coating thereon since it teaches every positively claimed element of the apparatus. Note it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ 2d 1647 (1987). With respect to claims 9, 11 and 13-14, Hattler et al teaches stent and a mandrel to support the stent wherein the mandrel extends the entire length of the catheter or stent (see column 4 lines 64-66). Hattler et al shows the mandrel is comprised of a member including integrally formed walls that have a shape

Art Unit: 1734

and length within the scope of the claims (see Figures 12-13 and 16). Hattler et al teaches at column 5 lines 10-15 that the catheter tube or stent supported on the mandrel is radially expandable. Although Hattler et al explicitly fails to teach the stents includes struts as set forth in newly amended claim 9 along with claims 11 and 13-14, it would have been inherent Hattler et al stent/catheter tube includes struts since stents have struts as evidenced by Tseng et al. Hattler et al is capable of supporting the catheter or stent during application of coating thereon since it teaches every positively claimed element of the apparatus. Note it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ 2d 1647 (1987). With respect to claims 1, 4-5 and 24-25, Hattler et al shows as depicted in Figures 1-3 a stent and a stent mandrel supporting the catheter or stent comprising: a first member (protrusions arranged at one end of the mandrel) to contact a first end of the stent; a second member (protrusions arranged at the opposite end of the mandrel) to contact a second end of the stent; and a third member connecting the first member to the second member and extending through a longitudinal bore of the stent, the third member having at least least three walls 34 and these wall 34 are shaped and/or sized to substantially prevent a coating from being formed on a luminal surface of the catheter or stent. Hattler et al shows the third member has a plurality of spikes and these spikes contact the luminal surface. Hattler et al teaches the divider extends the entire length of the catheter or stent (see column 4 lines 64-66). Although Hattler et al explicitly fails to teach the stents

Art Unit: 1734

includes struts as set forth in newly amended claims 1,4-5 and 24-25, it would have been inherent that Hattler et al stent/catheter tube includes struts since stents have struts as evidenced by Tseng et al. Hattler et al is capable of support the catheter or stent during application of coating thereon since it teaches every positively claimed element of the apparatus. Note it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ 2d 1647 (1987).

Claims 1,4-5,9,11,13-14,19 and 23-25 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hattler et al 4,846,791 with Tseng et al 6,364,903 cited to show inherency and, in any event, cited to show obviousness.

Hattler et al teaches in drawings which include Figures 12-13 stent or catheter tube and a mandrel to support the catheter or stent comprising: a member to penetrate at least partially into a longitudinal bore of a stent, the member including outwardly projecting integral walls disposed around the circumference of the mandrel, wherein each of the walls converge with its neighboring wall at an angle. Hattler et al teaches at column 5 lines 10-15 that the catheter tube or stent supported on the mandrel is radially expandable. Although Hattler et al explicitly fails to teach the stents includes struts as set forth in newly amended claim 23, it would have been inherent Hattler et al stent/catheter tube includes struts since stents have struts as evidenced by Tseng et al and, in any event, it would have obvious to support any known stent or catheter tube

including that disclosed by Tseng et al on the Hattler et al mandrel especially since Hattler infers his mandrel body is capable of accepting different configurations of stent or catheter tubes as inferred by Hattler et al disclosure of the catheter tube or stent at column 5 lines 10-15 and column 6 lines 45-52 for the obvious reason to expect similar end results – a catheter assembly capable of being insert into a blood vessel. Hattler et al is capable of supporting a catheter or stent during application of coating thereon since it teaches every positively claimed element of the apparatus. Note it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ 2d 1647 (1987). With respect to claim 19, Hattler et al teaches as depicted in the drawings which includes Figure 16 the design of a stent or catheter tube and mandrel to support the catheter or stent comprising: a member to penetrate at least partially into a longitudinal bore of a stent during the application of a coating substance, the member including 6 sides and each side wall surface is non-parallel with its neighboring side wall surface. Hattler et al teaches at column 5 lines 10-15 that the catheter tube or stent supported on the mandrel is radially expandable. Although Hattler et al explicitly fails to teach the stents includes struts as set forth in newly amended claim 23, it would have been inherent Hattler et al stent/catheter tube includes struts since stents have struts as evidenced by Tseng et al and, in any event, it would have obvious to support any known stent or catheter tube including that disclosed by Tseng et al on the Hattler et al mandrel especially since Hattler infers his mandrel body is capable of accepting different

Art Unit: 1734

configurations of stent or catheter tubes as inferred by Hattler et al disclosure of the catheter tube or stent at column 5 lines 10-15 and column 6 lines 45-52 for the obvious reason to expect similar end results – a catheter assembly capable of being insert into a blood vessel. Hattler et al is capable of support the catheter or stent during application of coating thereon since it teaches every positively claimed element of the apparatus.

Note it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ 2d 1647 (1987). With respect to claims 9, 11 and 13-14, Hattler et al teaches a stent or catheter tube and a mandrel which extends the entire length of the catheter or stent (see column 4 lines 64-66). Hattler et al shows the mandrel is comprised of a member including integrally formed walls that have a shape and length within the scope of the claims (see Figures 12-13 and 16). Hattler et al teaches at column 5 lines 10-15 that the catheter tube or stent supported on the mandrel is radially expandable.

Although Hattler et al explicitly fails to teach the stents includes struts as set forth in newly amended claims 9, 11 and 13-14, it would have been inherent Hattler et al stent/catheter tube includes struts since stents have struts as evidenced by Tseng et al and, in any event, it would have obvious to support any known stent or catheter tube including that disclosed by Tseng et al on the Hattler et al mandrel especially since Hattler infers his mandrel body is capable of accepting different configurations of stent or catheter tubes as inferred by Hattler et al disclosure of the catheter tube or stent at column 5 lines 10-15 and column 6 lines 45-52 for the obvious reason to expect similar

end results – a catheter assembly capable of being insert into a blood vessel. Hattler et al is capable of supporting the catheter or stent during application of coating thereon since it teaches every positively claimed element of the apparatus. Note it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ 2d 1647 (1987). With respect to claims 1, 4-5 and 24-25, Hattler et al shows as depicted in Figures 1-3 stent and a stent mandrel support supporting the catheter or stent comprising: a first member (protrusions arranged at one end of the mandrel) to contact a first end of the stent; a second member (protrusions arranged at the opposite end of the mandrel) to contact a second end of the stent; and a third member connecting the first member to the second member and extending through a longitudinal bore of the stent, the third member having at least least three walls 34 and these wall 34 are shaped and/or sized to substantially prevent a coating from being formed on a luminal surface of the catheter or stent. Hattler et al shows the third member has a plurality if spikes and these spikes contact the luminal surface. Hattler et al teaches the divider extends the entire length of the catheter or stent (see column 4 lines 64-66). Although Hattler et al explicitly fails to teach the stents includes struts as set forth in newly amended claims 1, 4-5 and 24-25, it would have been inherent that Hattler et al stent/catheter tube includes struts since stents have struts as evidenced by Tseng et al and, in any event, it would have obvious to support any known stent or catheter tube including that disclosed by Tseng et al on the Hattler et al mandrel especially since

Hattler infers his mandrel body is capable of accepting different configurations of stent or catheter tubes as inferred by Hattler et al disclosure of the catheter tube or stent at column 5 lines 10-15 and column 6 lines 45-52 for the obvious reason to expect similar end results – a catheter assembly capable of being insert into a blood vessel. Hattler et al is capable of support the catheter or stent during application of coating thereon since it teaches every positively claimed element of the apparatus. Note it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ 2d 1647 (1987).

Claims 6-8 and 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hattler et al in view of Tseng et al 6,364,903.

Hattler et al and Tseng are applied for the reasons noted above. Hattler et al fails to teach the cross-section of the third member is within the scope of claims 7-8. Hattler et al teaches the third member can have shapes other than triangular such as cross-shaped or star-shaped. However, it would have been obvious to modify the mandrel in the Hattler et al stent and mandrel combination as set forth above by providing the third member with a shape within the scope of claims 7-8 since Hattler et al teaches the third member can have shapes other than triangular such as cross-shaped or star-shaped obviously to provide greater support of the catheter or stent. With respect to claim 6, Hattler et al fails to teach that the spikes do not contact the luminal of the stent or catheter. Hattler et al teaches that the geometry of the divider may or may not require protrusions to provide support necessary to prevent collapse of the lumen within the

Art Unit: 1734

catheter or stent. Therefore it would have been obvious to modify the Hattler et al mandrel such that the spikes of the third member do not have to touch or contact the luminal of the stent as long as the number of protrusions on the third member are sufficient to prevent collapse of the luminal within the catheter or stent for the obvious reason of providing a plurality of discrete support points – enable one to provide continued support for the catheter despite wear of the one of the discrete protrusions. With respect to claims 20-22, Hattler et al teaches as depicted in the drawings which include Figure 3 the design of a mandrel to support a catheter or stent comprising: a core section having at least three sides and a wall extending from each of the sides in an outwardly direction. Hattler et al shows the walls are triangular in cross section and core have a shape within the scope of the claims. Hattler et al fails to teach that the core is solid and the wall is coupled to and extending from each of the sides in an outwardly direction. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the mandrel by coupling a wall to each of the sides of the Hattler et al core section in the Hattler et al stent and mandrel combination as set forth above since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177,179. Further, Hattler et al teaches at column 6 lines 66-67 that the divider can be either hollow or solid. Therefore, it would have been obvious given the modified Hattler et al apparatus as discussed above to construct the core section as a solid core section rather than a hollow core section since Hattler et al teaches at column 6 lines 66-67 that the divider can be either hollow or solid and

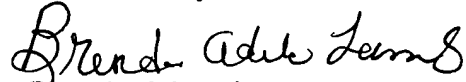
obvious to do so to increase the structural stability of the mandrel. Hattler et al is capable of support the catheter or stent during application of coating thereon since it teaches every positively claimed element of the apparatus. Note it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ 2d 1647 (1987).

Applicant's arguments filed 7/23/2006 have been fully considered but they are not persuasive.

Applicant's argument that Hattler et al fails to teach a catheter is not a stent comprising a plurality of struts is found to be non-persuasive. First of all, it is noted that the American Heritage Dictionary of the English Language, Fourth Ed. (2000) defines a **stent** as "a slender thread, rod, or **catheter** inserted into a tubular structure, such as a blood vessel, to provide support during or after anastomosis." Therefore, as discussed above, although Hattler et al explicitly fails to teach the stents includes struts, it would have been inherent Hattler et al stent/catheter tube includes struts since stents have struts as evidenced by Tseng et al and, in any event, it would have obvious to support any known stent or catheter tube including that disclosed by Tseng et al on the Hattler et al mandrel especially since Hattler infers his mandrel body is capable of accepting different configurations of stent or catheter tubes as inferred by Hattler et al disclosure of the catheter tube or stent at column 5 lines 10-15 and column 6 lines 45-52 for the obvious reason to expect similar end results – a catheter assembly capable of being insert into a blood vessel.

Art Unit: 1734

Any inquiry concerning this communication should be directed to Brenda A. Lamb at telephone number (571) 272-1231. The examiner can normally be reached on Monday-Tuesday and Thursday-Friday with alternate Wednesday off.

A handwritten signature in cursive script that reads "Brenda A. Lamb".

Brenda A Lamb
Examiner
Art Unit 1734